Sustainability in Pharma Manufacturing and the Pharma Supply Chain

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Ghent University, EnVOC

ISPE Belgium Environmental Sustainability Event,
Wavre - Belgium, February 26th 2015

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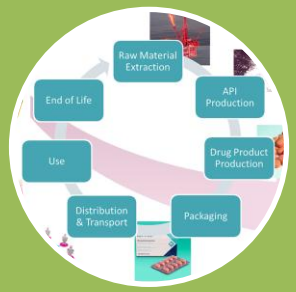
1. Introduction: Research group and focus

Ghent University: Department of Sustainable Organic Chemistry and Technology

Analytical Environmental Organic Chemistry

Abatement of Organic Micropollutants



Clean Technologies, Process Engineering and LCA

Environmental Resource Management

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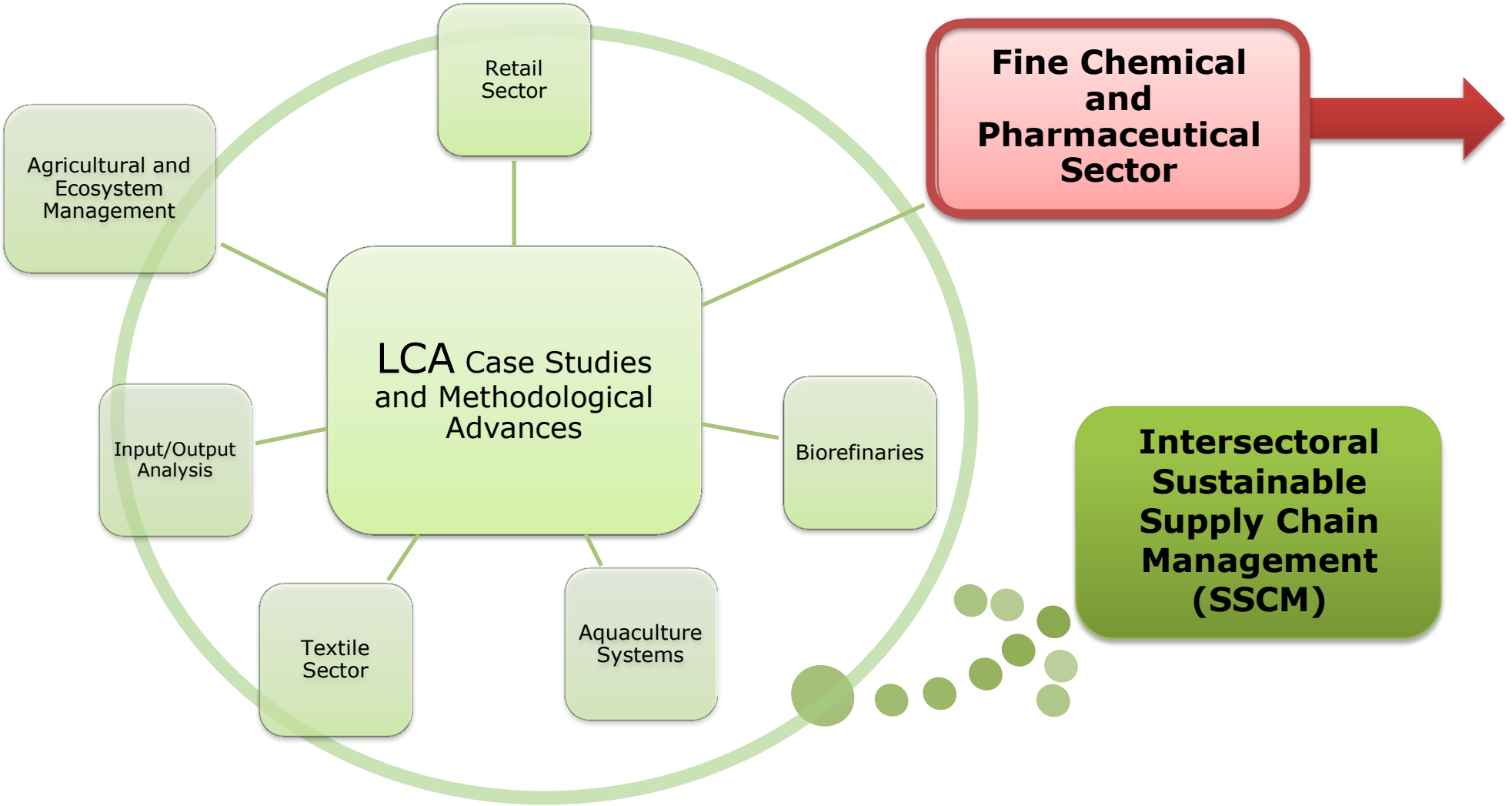
1. Introduction: Research group and focus



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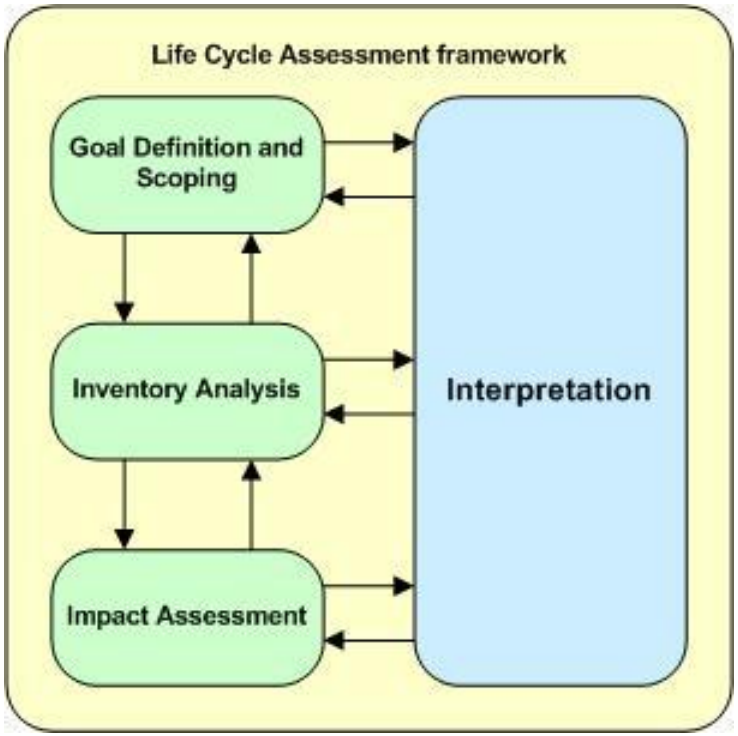
2. Life Cycle Assessment as a Tool for Assessing Environmental Sustainability

- Assessment of the potential environmental impact of a given product or service within the production chain and throughout its lifespan.
  - Goal and Scope Definition
  - Life Cycle Inventory (LCI)
  - Life Cycle Impact Assessment (LCIA)
  - Interpretation



A Major Challenge for Pharma: Data Management in LCI

- Most time-consuming step
- DATA MANAGEMENT to reduce cost of LCA
- PLC → MES → SAP

Innovation

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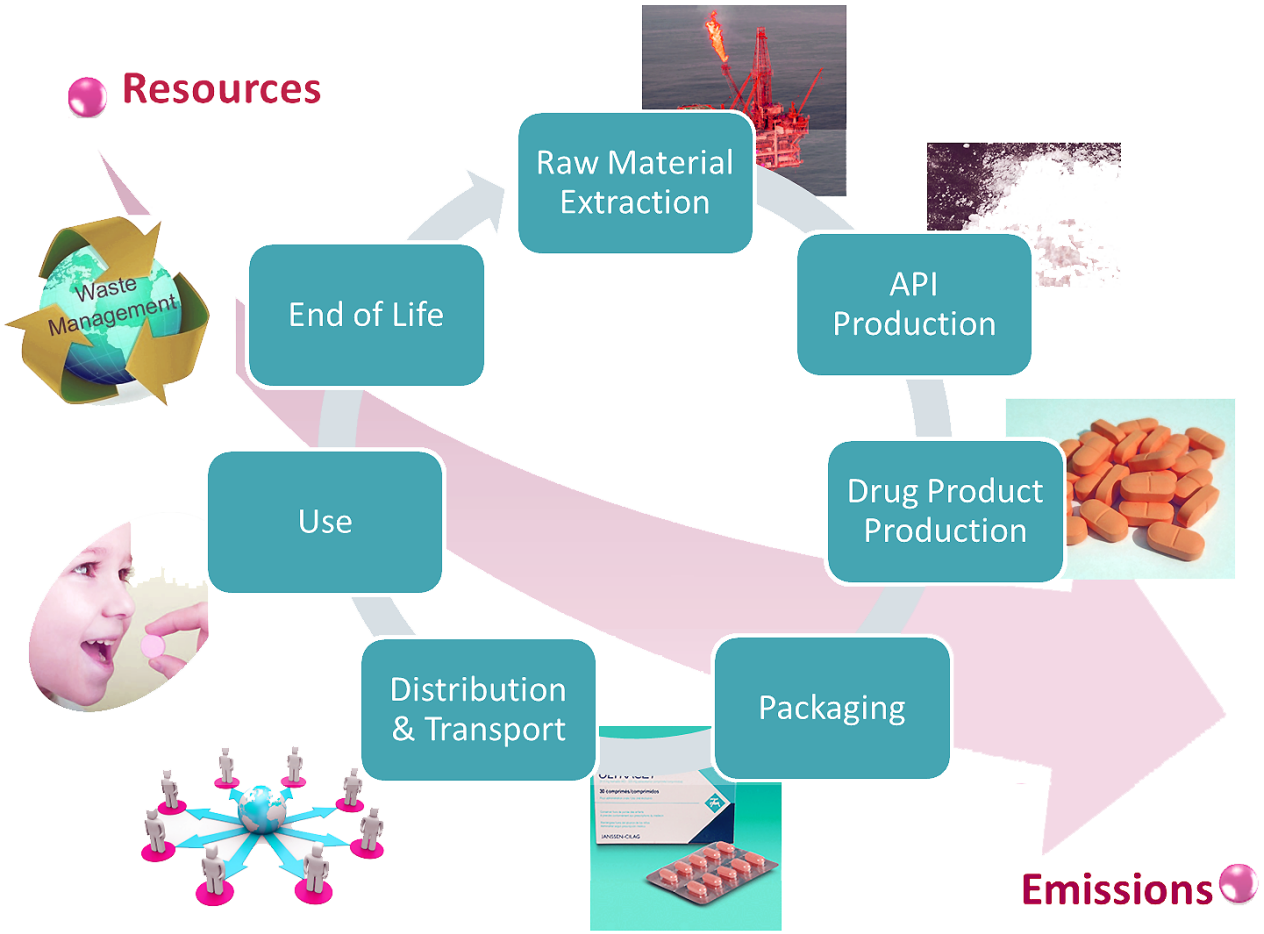
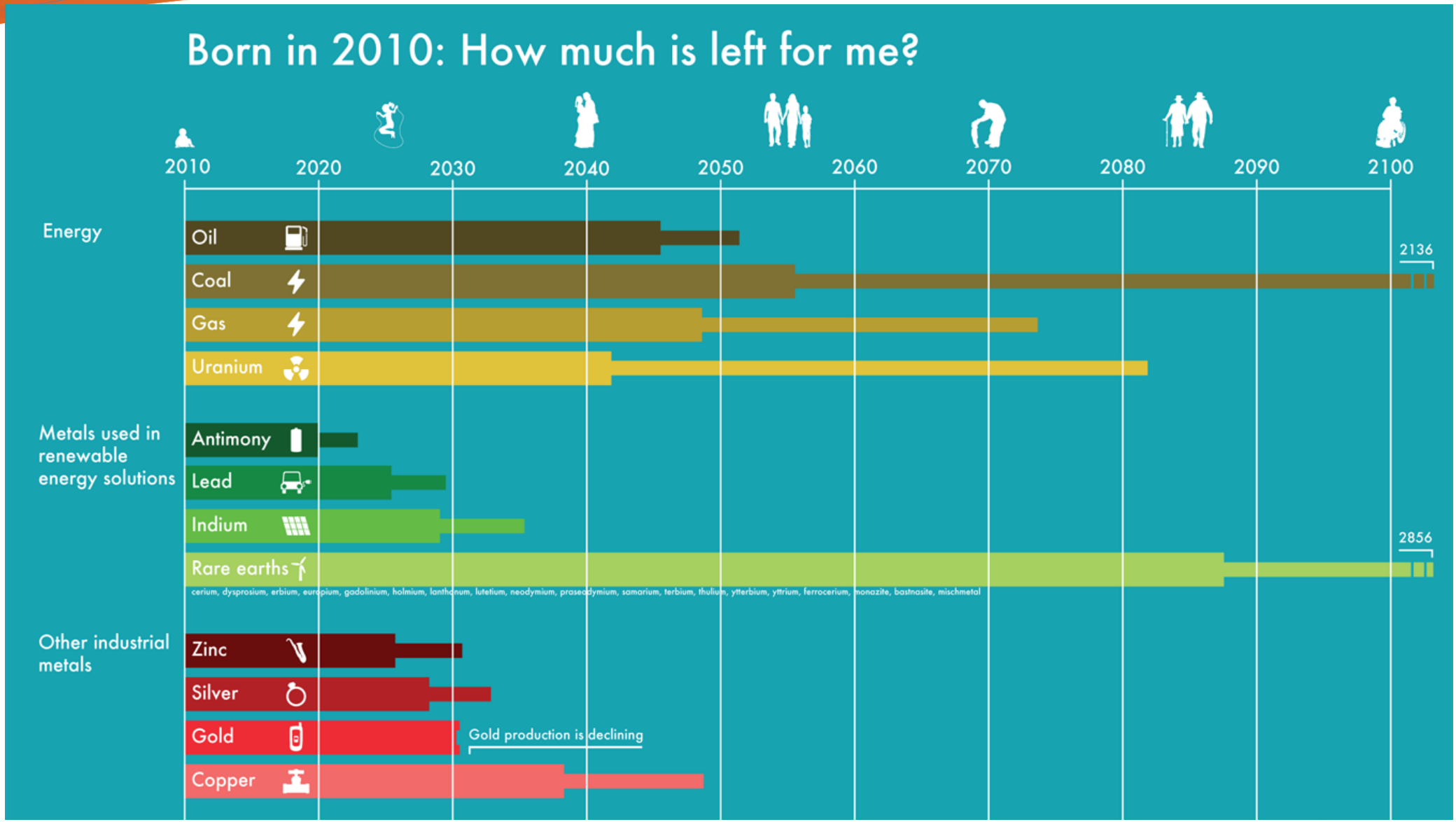
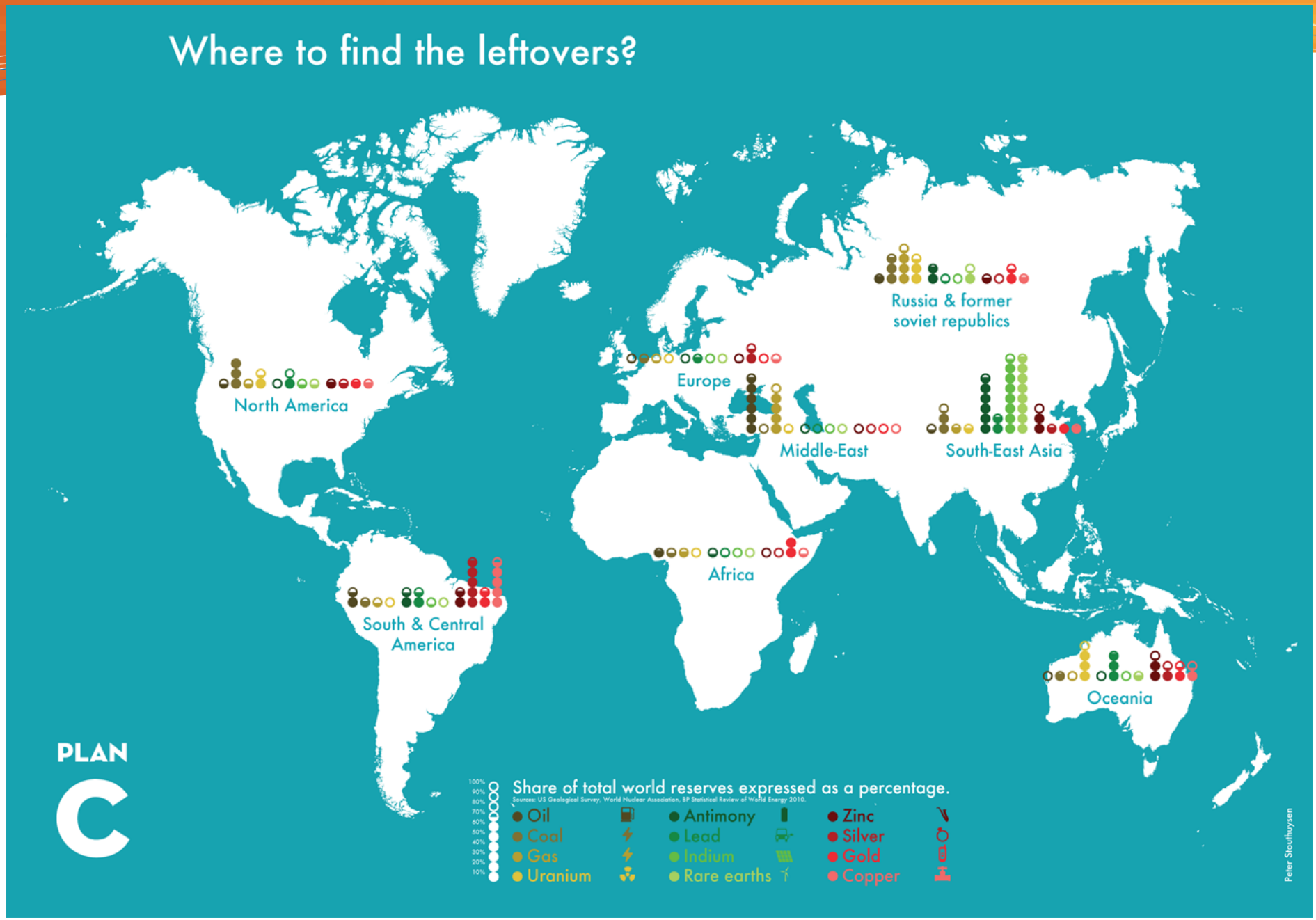
Life Cycle Impact Assessment (LCIA): What should be our FOCUS?




Born in 2010: How much is left for me?
2010
2020
2030
2040
2050
2060
2070
2080
2090
2100
Energy
Oil
Coal
Gas
Uranium
2136
Metals used in renewable energy solutions
Antimony
Lead
Indium
Rare earths
2856
cerium, dysprosium, erbium, europium, gadolinium, holmium, lanthanum, lutetium, neodymium, praseodymium, samarium, terbium, thulium, ytterbium, yttrium, ferrocerium, monazite, bastnasite, mischmetal
Other industrial metals
Zinc
Silver
Gold
Gold production is declining
Copper



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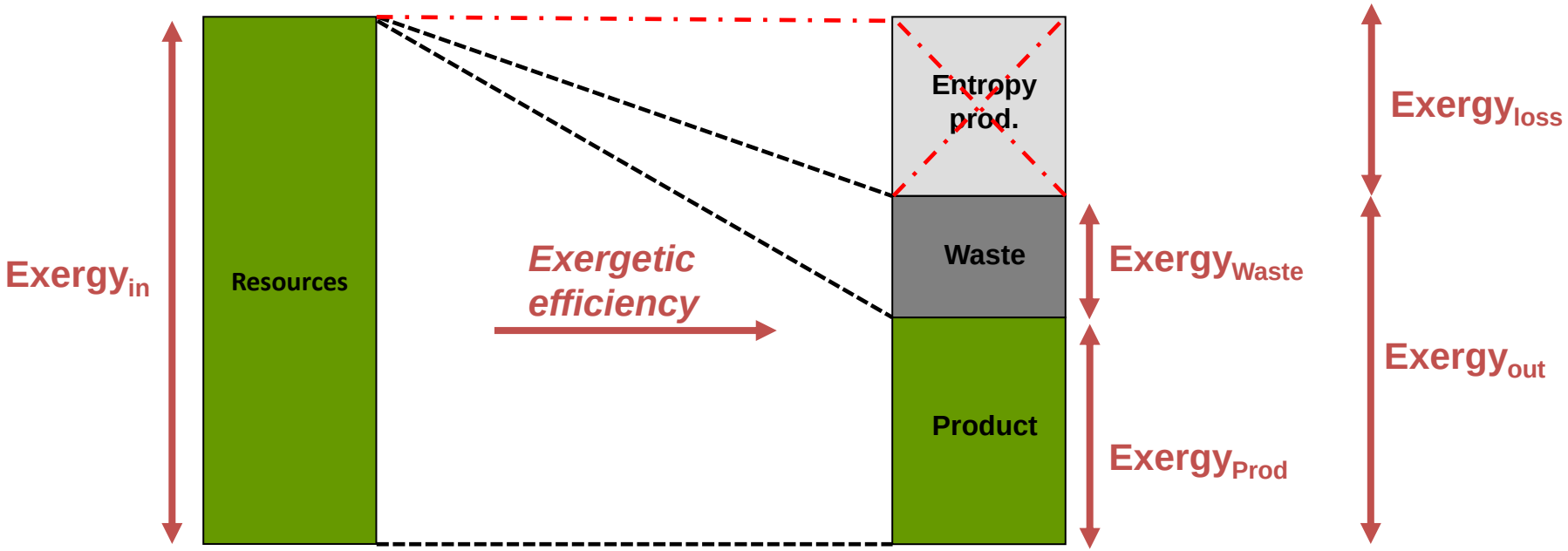
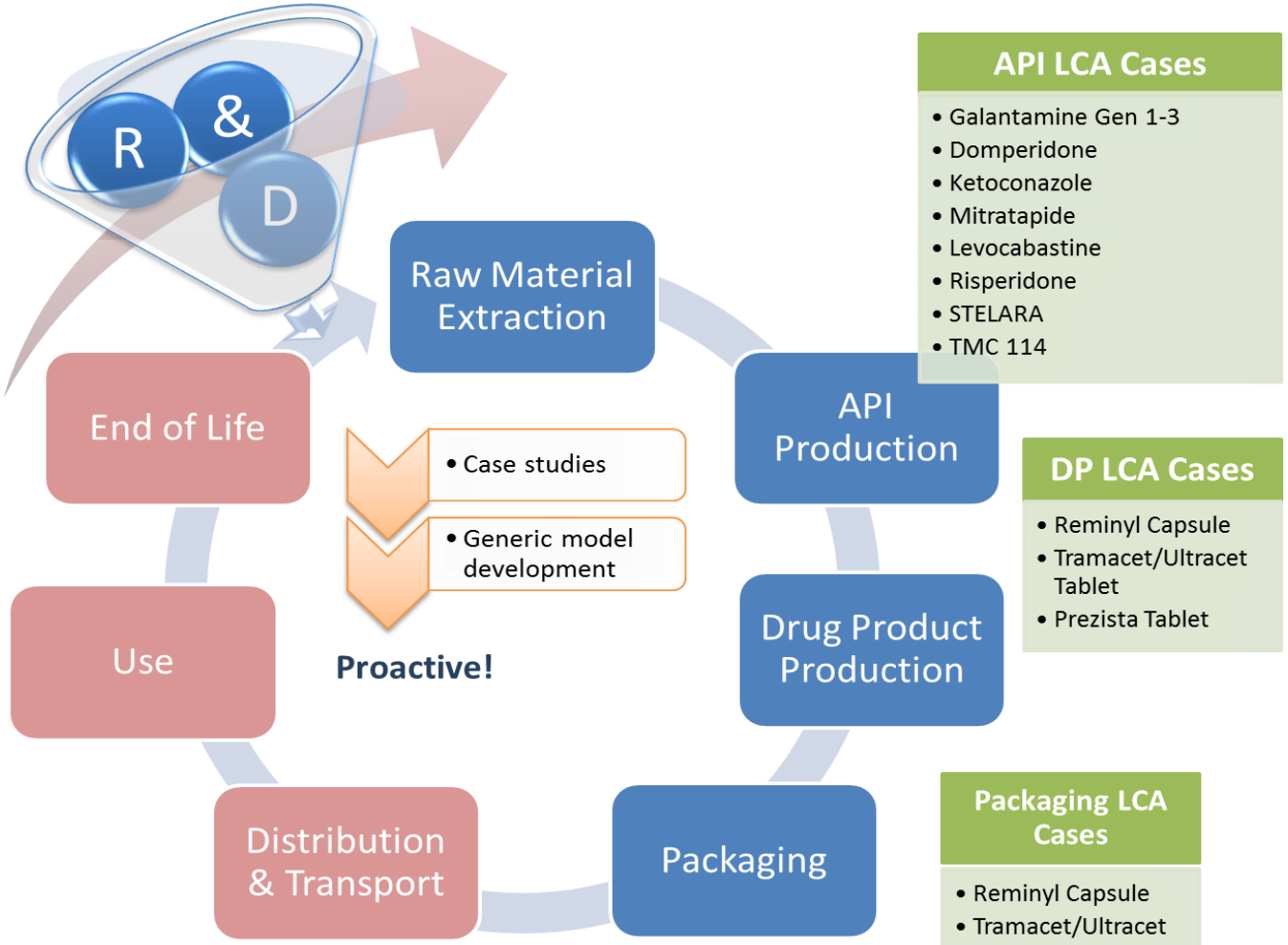
Resources: How to quantify?

- How to quantify all different kinds of resource? Energetic, physical resources?
  → Exergy Analysis (**EA**) & Exergetic Life Cycle Analysis (**ELCA**, e.g. CEENE Method)



(Dewulf et al., Environ. Sci. Technol., 2008)

JNJ-UGENT Research Portfolio:



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Exemplary Case Study:

Exergetic sustainability assessment of **batch versus continuous** wet granulation based pharmaceutical **tablet manufacturing**: a cohesive analysis at three different levels

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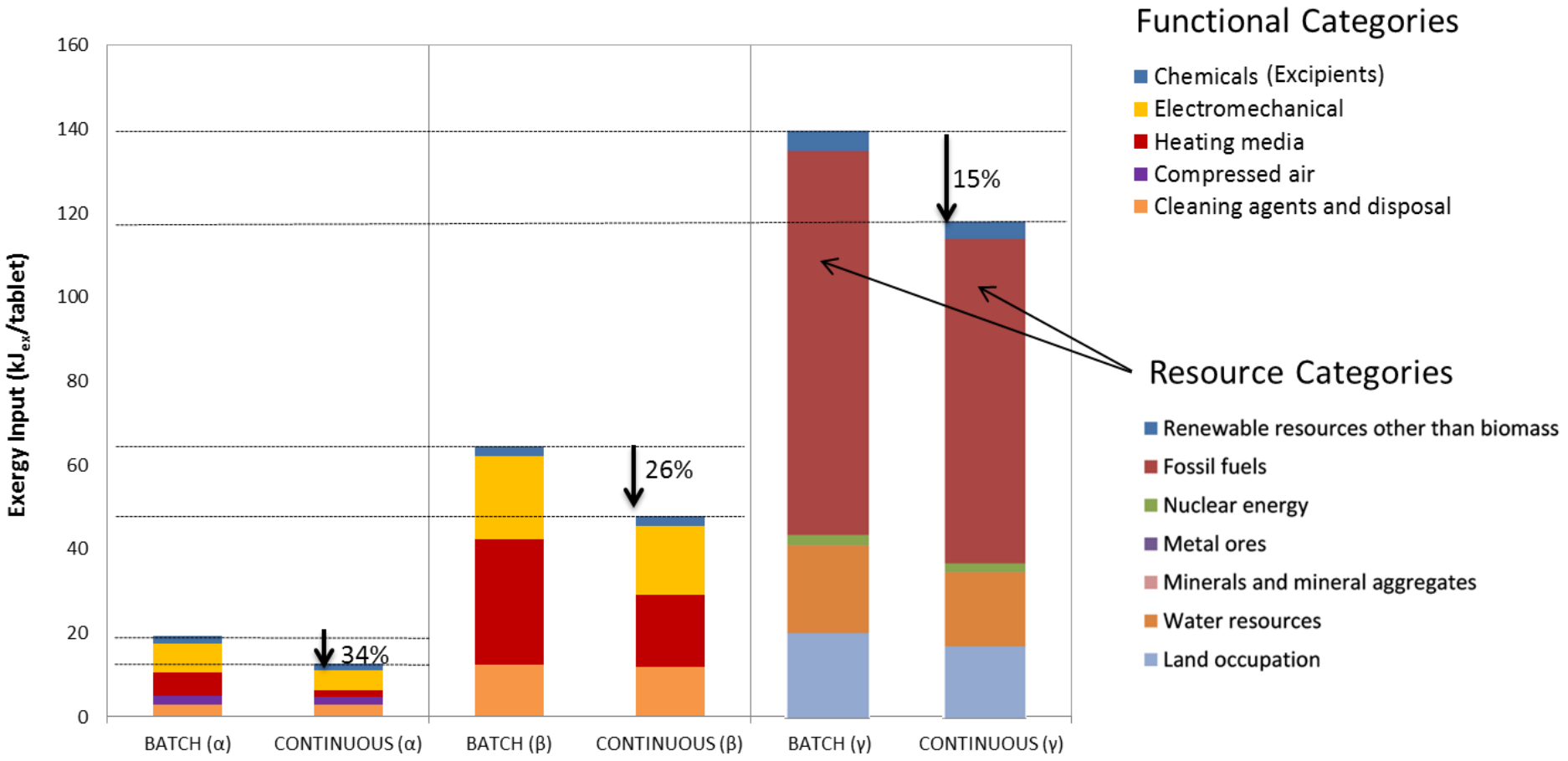
De Soete *et al.*, 2013. Green Chemistry.

Exemplary Case Study: Batch vs. Continuous Granulation



- **Tablet CEENE: 65% fossil, 15% water resources, 15% land occupation/biomass, 5% renewables resources other than biomass**

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Methodological Advancements: Streamlined LCA

Life Cycle Based Resource Footprinting of Active Pharmaceutical (API) Synthesis Steps

1) Hotspot Analysis

2) Product Group approach

Product specific approach

API	# BPRs	# BOs
(A) Domperidone	10	492
(B) Risperidone	7	502
(C) Ketoconazole	8	733
(D) Mitratapide	7	471
(E) Levocabastine	8	641

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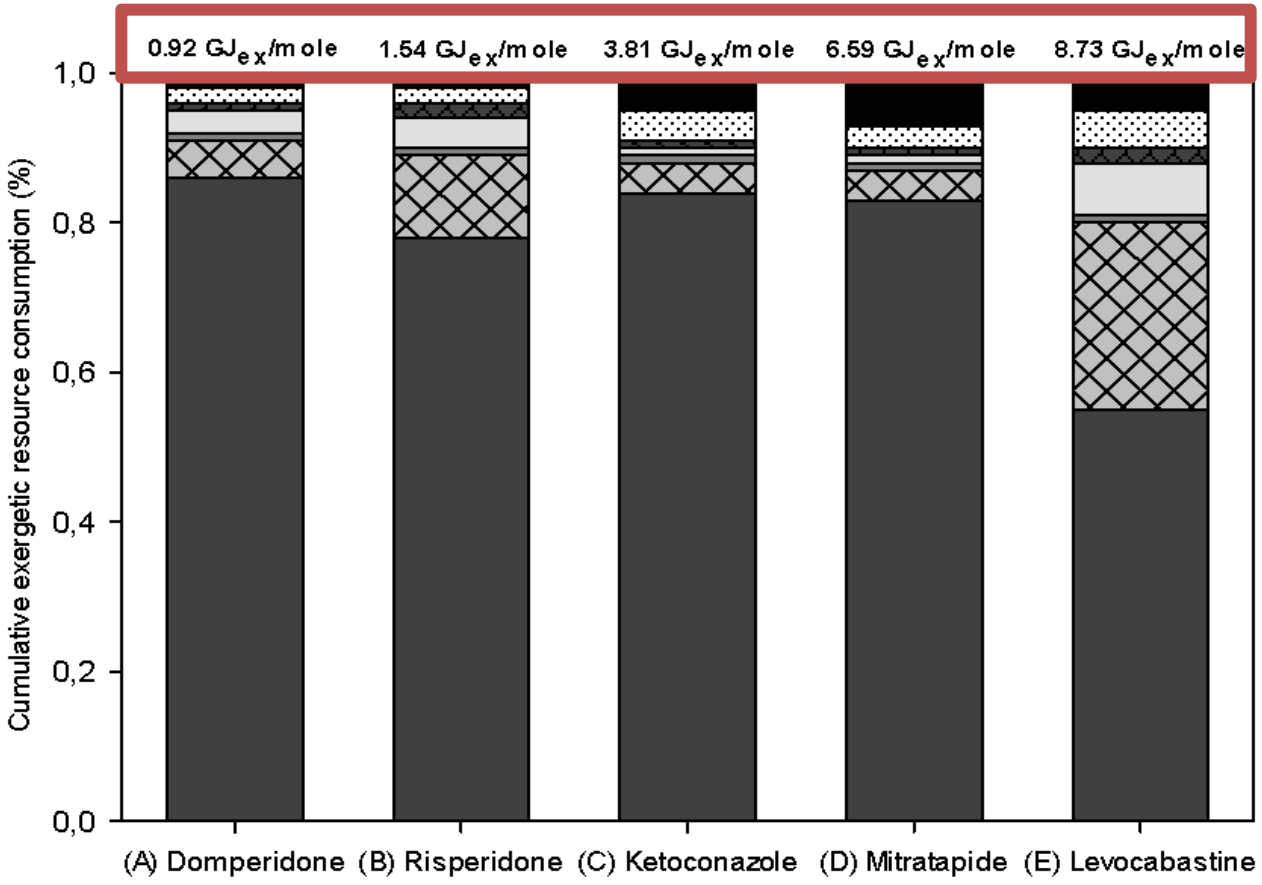
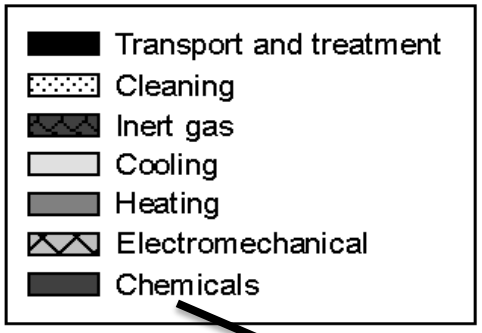
Methodological Advancements: Streamlined LCA

- Average value of cumulative resource consumption data
- Backwards stepwise linear regression modeling:
  - 15 candidate predictor variables, selected based on:
    - Readily availability of data in business ERP systems
    - Expert knowledge
  - 4 predictor variable categories:
    - Process-oriented resource indicators (4)
    - Process operational variables (2)
    - Equipment variables (6)
    - Chemistry variables (3)

1) Hotspots identification





Subdivision of Chemicals

OS: 67.2%

BB: 22.5%

Reagents: 10.2%

Catalysts: 0.1%

Environmental Science & Technology

De Soete et al., 2014, ES&T

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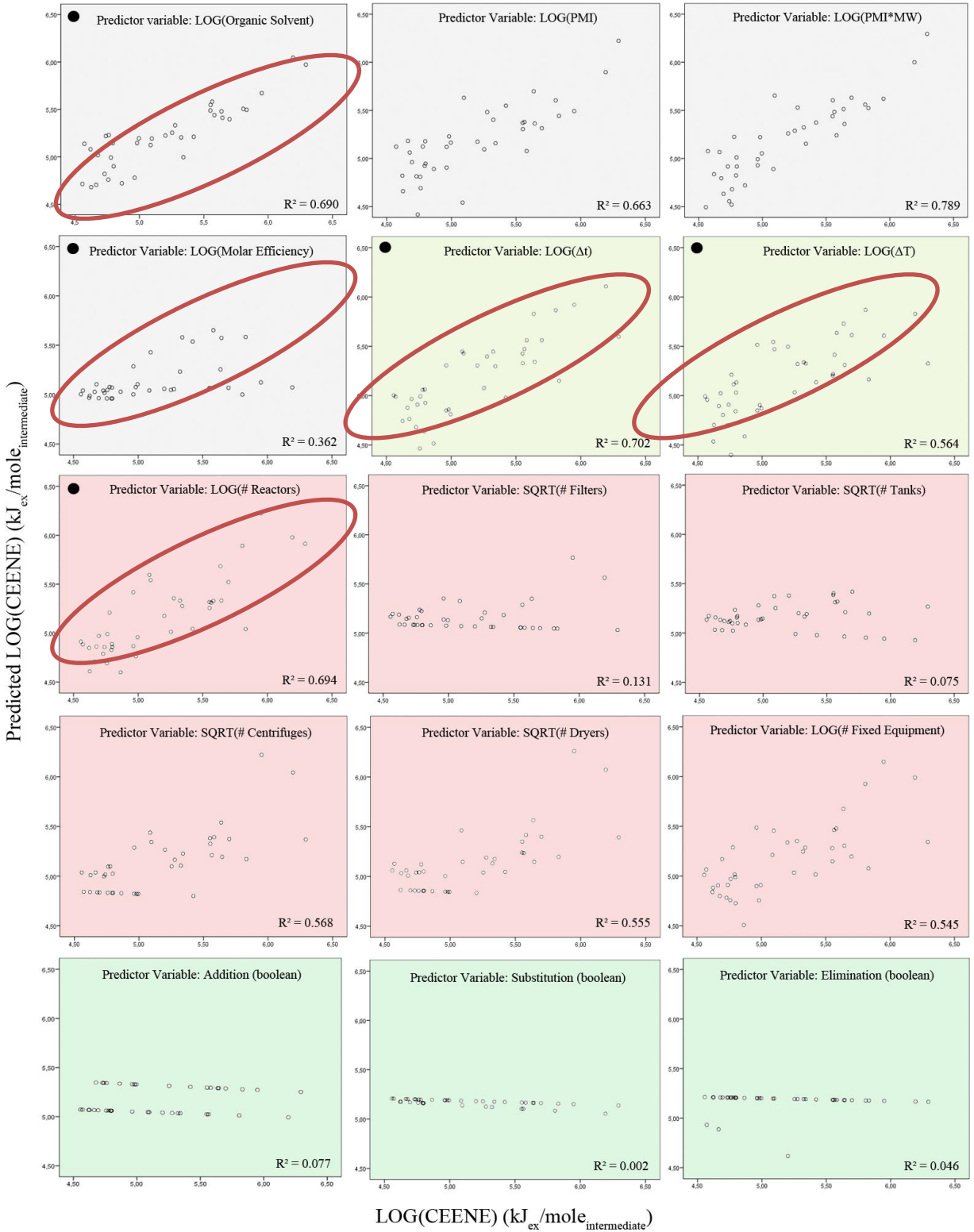
2)



Selected Predictors:

Organic Solvent use
Molar Efficiency
Δt
ΔT
Reactors

De Soete et al., 2014, ES&T

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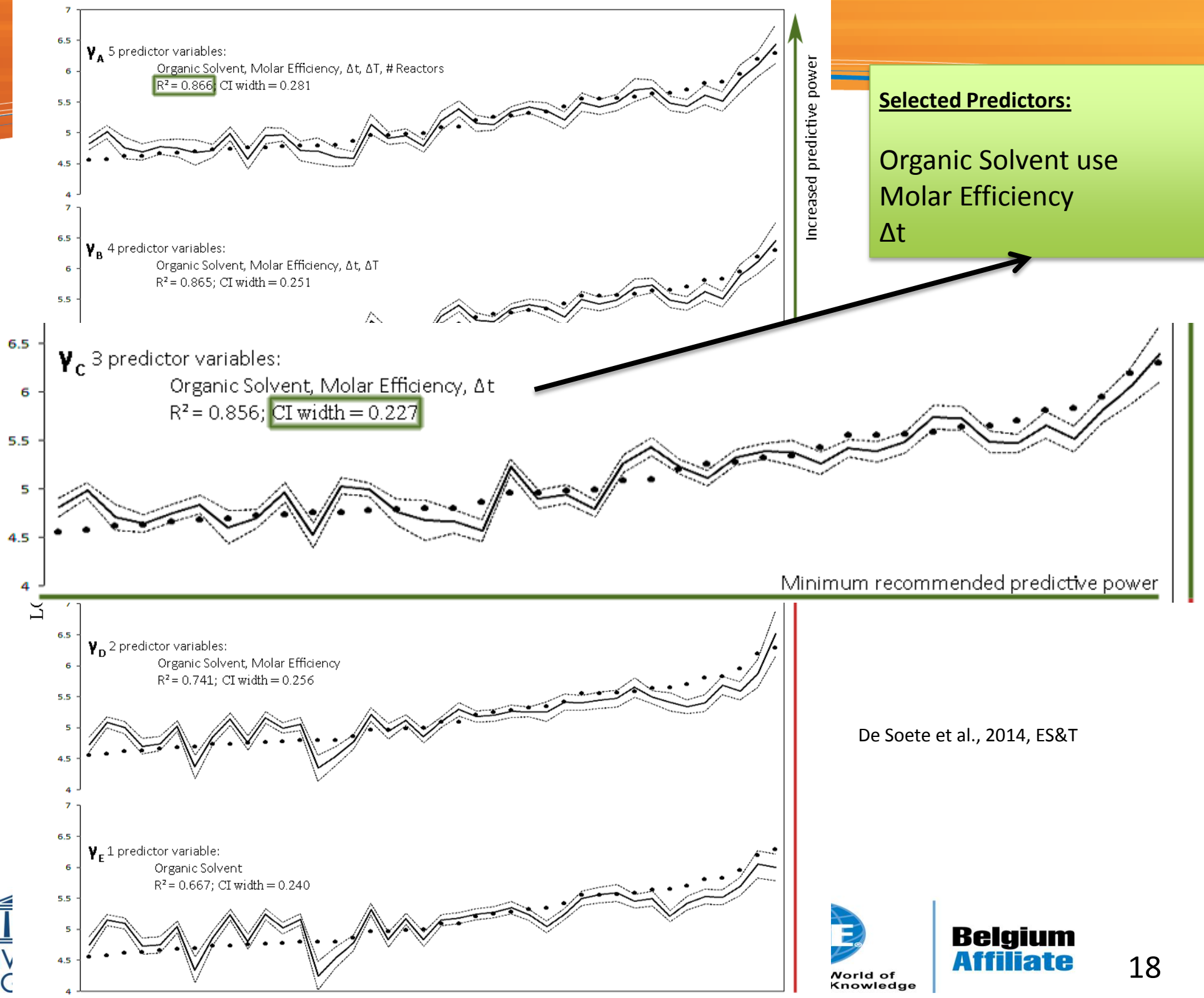
2)



Selected Predictors:

Organic Solvent use
Molar Efficiency
Δt

De Soete et al., 2014, ES&T

3. Policy visions & Compliance

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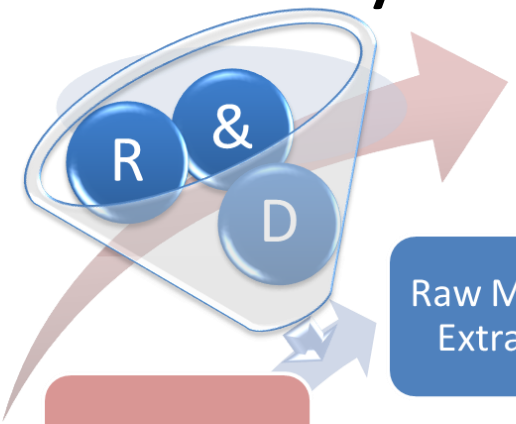
3. Policy visions & Compliance



Raw Material Extraction

API Production

Drug Product Production

Packaging

Distribution & Transport

Use

End of Life

- Case studies
- Generic model development

Proactive!

API LCA Cases

- Galantamine Gen 1-3
- Domperidone
- Ketoconazole
- Mitratapide
- Levocabastine
- Risperidone
- STELARA
- TMC 114

DP LCA Cases

- Reminyl Capsule
- Tramacet/Ultracet Tablet
- Prezista Tablet

Packaging LCA Cases

- Reminyl Capsule
- Tramacet/Ultracet Tablet
- Prezista Tablet

European Commission

No Guide

ISO Standard

ILCD Handbook situation A/C1

Environmental Footprint Guide

PEFCR/ OEFSR

(Tools, database)

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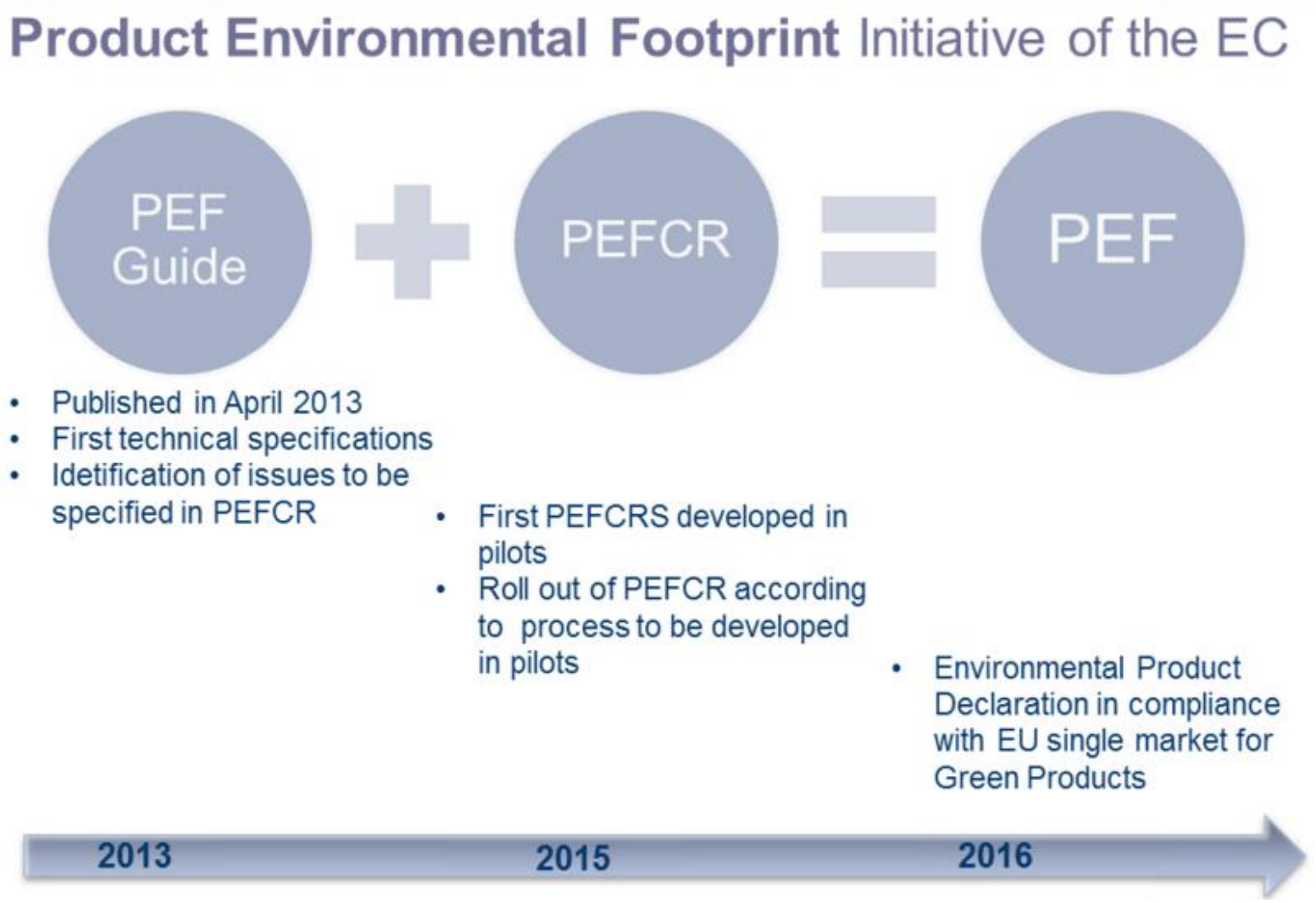

4. Future Outlook

- **Improved data acquisition systems** from sensors, PLCs, etc. to central enterprise data systems (e.g. SAP, Infor LN)
- Alignment of Pharmaceutical Sector through **EU PEF Pharma Pilot**
- Focus on **Human Health burden/benefit**
- Sustainable Supply Chain Management (**SSCM**)
  - It makes little sense to optimise in-house production without a proper procurement policy!! → Coupling organisation's ERP systems

Thank You! Q/A

Sustainability in Pharma Manufacturing and the Pharma Supply Chain

Q/A

Contact: Wouter.DeSoete@UGent.be

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